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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/816,688 | 03/22/2001 | Katherine A. High | 018743-0278737 | 5212 |
| 7590 | 01/12/2006 | | EXAMINER | |
| Robert Bedgood Pillsbury Winthrop LLP 101 W Broadway Suite 1800 San Diego, CA 92101 | | | WHITEMAN, BRIAN A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1635 | |
| DATE MAILED: 01/12/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/816,688 | HIGH ET AL. | |
| | Examiner | Art Unit | |
| | Brian Whiteman | 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-63 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-63 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Claims 1-63 are pending.

Claim 9 contains an amino acid sequence missing a corresponding SEQ ID NO that is located in the CRF. Suggest inserting the SEQ ID NO after the amino acid sequence.

Claims 33, 34, and 36 and claims dependent therefrom contain an improper Markush group and each subject matter (polypeptide or composition comprising a recombinant polynucleotide) recited in the claims will be placed into a separate group.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 6-32, 34, 35, 41, drawn to a composition comprising a recombinant polynucleotide encoding a modified blood clotting factor that is a vitamin K-dependent procoagulant, classifiable in class 536, subclass 23.1.
- II. Claims 1-3, 5-12, 15-17, 21-32, 35, drawn to a composition comprising a recombinant polynucleotide encoding a modified blood clotting factor that is a vitamin K-dependent anticoagulant, classifiable in class 536, subclass 23.1.
- III. Claim 33 and 34, drawn to a polypeptide, classifiable in class 530, subclass 350.
- IV. Claim 36-40, drawn to a composition comprising a polynucleotide and a cell, classifiable in class 435, subclass 455.
- V. Claim 36-40, drawn to a composition comprising a polypeptide and a cell, classifiable in class 514, subclass 2.

VI. Claims 42-48 and 50-63, drawn to a gene therapy method wherein the disorder is amendable to treatment with Factor VII, Factor VIII or Factor IX, classifiable in class 424, subclass 93.2.

VII. Claims 42, 45, 49, 56, 58, 59, 60, 62, and 63, drawn to a gene therapy method for treating Bernard-Soulier's thrombasthenia, classifiable in class 424, subclass 93.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the polynucleotide in group I and II and the polypeptide in group III are patentably distinct. Polypeptides, which are composed of amino acids, and polynucleotides which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. The polynucleotide of Group I encodes a procoagulant protein and the polynucleotide encodes an anticoagulant protein. The polynucleotide in group I does not require the polynucleotide in group II. Furthermore, searching the inventions of groups I, II, and III together would impose a serious search burden. In the instant case, the search of the polypeptide and the polynucleotides are not coextensive. The inventions of Groups I and II and Group III have a separate status in the art shown by their different classifications. There is search burden in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would

not have described the polynucleotides. Similarly, there may have been “classical” genetic papers which had no knowledge of the polypeptide but spoke to the polynucleotide. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of groups I and II together.

Inventions I and VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of group I can be used to make recombinant proteins as opposed to its use in gene therapy in either group VI or VII.

Searching the inventions of Groups I and Groups VI and VII together would impose serious search burden. The invention of groups I and Groups VI and VII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotide and the method of gene therapy using the polynucleotide are not coextensive. Moreover, even if the polynucleotide product were known, the method of gene therapy using the product may be novel and unobvious in view of the preamble or active steps.

Inventions I and V are unrelated because the product of group I is not used or otherwise involved in the composition of group V.

Inventions II and V are unrelated because the product of group II is not used or otherwise involved in the composition of group V.

Inventions II and either VI and VII are unrelated because the product of group II is not used or otherwise involved in the process of group VI or VII.

Inventions III and IV are unrelated because the product of group III is not used or otherwise involved in the process of group IV.

Inventions III and either VI and VII are unrelated because the product of group III is not used or otherwise involved in the process of group VI or VII.

Inventions IV and either VI and VII are unrelated because the product of group IV is not used or otherwise involved in the process of group VI or VII.

Inventions V and either VI and VII are unrelated because the product of group V is not used or otherwise involved in the process of group VI or VII.

Inventions IV and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the blood clotting factor can be a vitamin K-dependent anticoagulant protein or selected from Factor VII, Factor IX, and Factor X. The subcombination has separate utility such as in a method of producing recombinant proteins in vitro.

Inventions IV and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the blood clotting factor can be a vitamin K-dependent procoagulant protein.

The subcombination has separate utility such as in a method of producing recombinant proteins in vitro.

Inventions V and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the blood clotting factor can be a vitamin K-dependent procoagulant protein or an anticoagulant protein. The subcombination has separate utility such as in a method of producing recombinant antibodies.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. A gene therapy method wherein the disorder is amenable to treatment with Factor VII, Factor VIII or Factor IX (group VI) and a gene therapy method for treating Bernard-Soulier's thrombasthenia (group VII) are all unrelated as they comprise distinct steps and utilize products which demonstrates that each method has a different mode of operation. Each invention performs this function using a different subject. Moreover, the methodology and materials necessary for each disorder differ significantly for each of the materials. Therefore, each method is divergent in materials and steps. For these reasons the Inventions VI and VII are patentably distinct. Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups VI and VII require a

different subject. As such, it would be burdensome to search the inventions of Groups VI and VII together.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.**

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the

process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and the search required for each Group listed above is not required for any other Group listed above and the search for each group is not co-extensive, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

If applicant elects either group I or group II, an election of species is required

This application contains claims directed to the following patentably distinct species of the claimed invention: proteolytic cleavage site comprises SEQ ID NO: 3, SEQ ID NO: 1 or SEQ ID NO: 2.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: the vector comprises an adeno-associated virus, adenovirus, retrovirus, parvovirus, reovirus, rotavirus, or a herpes virus.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 29 and 30 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE - Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Brian Whiteman
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